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EXAMINER

SWARTZ, RODNEY P

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

1. Applicant's Response to Final Office action, received 28 January 2009, is acknowledged.
2. Claims 22-48 are pending and under consideration.

Rejections Maintained

3. The rejection of claims 22-48 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is maintained.

Applicant argues that the specification does enable the instant claims because the various examples teach administration of a pharmaceutical composition comprising an effective amount of mycobacterium w or a constituent of mycobacterium.

The examiner has considered applicant's argument, but does not find it persuasive because while the examples do recite treatment, management or prevention of lung disease by administration of "Mycobacterium w or a constituent of Mycobacterium w", the specification does recite 8 different preparations.

Example 4 utilized a pharmaceutical composition comprising heat killed Mycobacterium w (as provided in Example 1A) at a dosage of 0.2 ml per week administered intradermally initially followed by a dosage of 0.1 ml per week administered intradermally; both dosages were administered at the interval of one per week. By four weeks patient became asymptomatic and number of drugs were gradually discontinued.

Example 5 utilized heat killed Mycobacterium w (as provided in Example 1A) at a dosage of 0.1 ml administered intradermally; the dosage was administered at the interval of one per fortnight. However, the length of treatment was not stated.

Example 6 utilized heat killed Mycobacterium w containing pharmaceutical compositions (as provided in Example 1A). It was administered as a dosage of 0.1 ml through nebuliser; the

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dosage was administered at the interval of one per week. However, the length of treatment was not stated.

Example 7 utilized 0.1 ml of Mycobacterium w containing compositions (as provided in Example 1A and 1D of this invention) which were added to the therapy and observed for another three months. However, the example does not recite which composition was utilized and the interval of treatments.

Example 8 utilized a dosage of 0.1 ml of Mycobacterium w containing compositions (as provided in Example 1A and 1D) were added to the therapy and observed for another three months. The dosage was administered intradermally every fortnight for three months. However, the example does not indicate which composition was utilized or if both were utilized, how each composition was utilized.

The claims are drawn to Mycobacterium w "or" "a" constituent of Mycobacterium w, and not to heat killed Mycobacterium nor sonicated Mycobacterium w (as taught in the examples). In addition, due to the unclear regimens concerning which composition or the intervals and length of treatment in the examples, the enablement of the instant claims remain insufficient.

Applicant argues that the Declarations of Dr. Khamar and Dr. Lamberti support the examples and provide further clarification of the composition used and the dosage and interval of treatments.

The examiner had considered the Declarations, but does not find them further persuasive because neither provides all of the necessary information for enablement of the instant claims. Dr. Khamar states which compositions are utilized in the examples, but does not state the interval or length of such treatments. Dr. Lamperti states which compositions were utilized, but does not indicate the length of such treatments.

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Therefore, the teachings of the application and the submitted Declarations remain insufficient for the scope of the instant claims.

Conclusion

4. Claims 22-48 remain finally rejected.
5. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

February 17, 2009